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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,201	11/03/2003	Ray J. Wu	19603/4301 (CRF D-3082-03	4192
7590 07/05/2006			EXAMINER	
Nixon Peabody LLP Clinton Square P.O. Box 31051 Rochester, NY 14603-1051			PAGE, BRENT T	
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			1638	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/700,201	Applicant(s) WU ET AL.	
	Examiner Brent Page	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-83 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03/19/2004</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS 10/25/2004</u> . |

Election/Restrictions

Applicant's election with traverse of Group VII in the reply filed on 06/02/2006 is acknowledged. The traversal is on the grounds that the restricted groups did not pose an undue search burden to the Examiner.

The Examiner was persuaded on a search of the elected subject matter to withdraw the restriction requirement, and all claims 1-83 were examined on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15, 34-36, 40-42, 46-48 and 64 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are broadly drawn to a seed from a transgenic plant. However due to Mendelian inheritance of the transgene, some seeds produced by a transgenic plant will not have a copy of the transgene, and will thus be indistinguishable from naturally occurring seeds. Accordingly, the claims are drawn to a product of nature, which is non-statutory subject matter.

See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo inoculant Co.*, 233 U.S. 127 (1948), and *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931).

This rejection can be overcome by amendment of the claims to indicate that the seed comprises the transgene.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 7, 9-20, 21, 23, 25-52, 53, 55, 57-68, 69, 71 and 73-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn to transgenic plants, seeds and methods comprising transforming a plant with a nucleic acid encoding an enzyme for trehalose biosynthesis from any source.

In contrast, the specification only provides guidance for the transformation of plants with nucleic acids encoding trehalose phosphate synthase and trehalose phosphate phosphatase from the microbial sources, *E. coli* or *Z. rouxii*. The specification does not provide guidance for the transformation of plants with trehalose biosynthesis genes from any other sources.

The function of trehalose phosphate phosphatases is not known in all plant and animal species, and is therefore unpredictable. Vogel et al (The Plant Journal 1998, 13:673-683) disclose the screening and cloning of trehalose phosphate phosphatases from *Arabidopsis thaliana*. Vogel et al state, "While we provide evidence for the

Art Unit: 1638

occurrence of genes encoding a specific trehalose-6-phosphate phosphatase in plants, it remains to be seen where and when the enzymes, as well as their putative products, are actually present in plant tissues.” Vogel et al also state “We also envisage constitutive expression and antisense expression of AtTPPA and AtTPPB in *Arabidopsis* in order to elucidate further the role of these two novel genes, as well as trehalose metabolism in general, in plants.” In addition to the unpredictability of the function of plant-derived trehalose phosphate phosphatases developmentally, it is also unknown whether plants produce constitutively, or otherwise, amounts of trehalose phosphate synthase that may affect trehalose biosynthesis endogenously in the host plant. Vogel et al further state, “Indeed, among the EST of *Arabidopsis* and rice there are homologues of yeast and bacterial trehalose-6-phosphate synthases. However, it still has to be shown that one or more of these homologues is functionally active.” Given the unpredictability in the state of the art, it is not known whether plants transformed with trehalose phosphate phosphatase genes from sources other than *E. coli* would result in the same effect as plants transformed with *E. coli*-derived trehalose phosphate phosphatase genes.

The effect of the expression and function of trehalose phosphate biosynthesis genes on transformed plants is unpredictable. Goddijn et al (US Patent 6,833,490) disclose a tobacco plant transformed with a TPP gene under control of the constitutive 35ScaMV promoter. Goddijn et al found that the expression of TPP in all plant parts caused a stunted phenotype in tobacco plants (see column 28, Example 2, for example). Romero et al (*Planta*, 1997 201:293-297) disclose a tobacco plant

transformed with the yeast trehalose-6-phosphate synthase gene. Romero et al found that many deleterious effects were encountered when trehalose accumulated due to the expression of trehalose biosynthesis genes (see page 295 first paragraph). Romero et al state, "A large fraction (40%) of F₀ trehalose-accumulating plants exhibited different degrees of phenotypic change, related to loss of apical dominance, stunted growth, lancet shaped leaves, and some sterility".

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to isolate functional trehalose phosphate phosphatase and trehalose phosphate synthase genes from all sources as claimed, and to evaluate their expression in transformed plants while avoiding deleterious effects.

Claims 1-5, 7, 9-20, 21, 23, 25-52, 53, 55, 57-68, 69, 71 and 73-79 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to transgenic plants, seeds and methods comprising transforming a plant with a nucleic acid encoding an enzyme for trehalose biosynthesis from any source.

In contrast, the specification only provides guidance for the transformation of plants with nucleic acids encoding trehalose phosphate synthase and trehalose

Art Unit: 1638

phosphate phosphatase from the microbial sources, *E. coli* or *Z. rouxii*. The specification does not provide guidance for the isolation or characterization of trehalose biosynthesis genes from any other sources, or plant transformation therewith.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a

Art Unit: 1638

functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties".

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claims 80-83 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plasmids contained in microorganisms. Since the plasmid contained in the microorganism is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be

Art Unit: 1638

readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the plasmid contained in the microorganism and it is not apparent if the microorganism is readily available to the public. Thus, a deposit is required for enablement purpose. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 9, 11, 13-21, 23, 25, 27, 29-42, 49-53, 55, 57, 59-69, 71, 73-74, 76-77 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Londesborough et al (US Patent 6130368).

The claims are drawn to a transgenic monocot plant or plant cell or protoplast transformed with a nucleic acid encoding an enzyme for trehalose biosynthesis, under control of an inducible promoter that confers low temperature stress, salt stress, or water stress tolerance to the plant wherein the monocotyledonous plant is a rice or wheat plant, wherein the inducible promoter is a RbcS promoter, wherein the plant is additionally transformed with a second nucleic acid encoding an enzyme for trehalose biosynthesis, wherein the transgenic monocot plant includes a nucleic acid encoding a selectable marker, a seed produced by said transgenic plant, a transgenic plant regenerated from said seed, protoplast or plant cell, a method of conferring low-temperature stress, water stress, or salt stress tolerance to a monocot plant comprising transforming monocot plant cell or protoplast with a nucleic acid encoding an enzyme for trehalose biosynthesis, wherein the monocotyledonous plant is wheat or rice and

wherein the plant cell or protoplast is transformed with a second nucleic acid encoding an enzyme for trehalose biosynthesis, and wherein the method of transformation is particle bombardment, or *Agrobacterium* mediated. The claims are further drawn to the methods and transformed plants and cells described above wherein the enzyme for trehalose biosynthesis is trehalose-6-phosphate synthase or trehalose-6-phosphate phosphatase.

Londesborough et al teach a monocotyledonous plant transformed with both the yeast trehalose-6-phosphate synthase and yeast trehalose-6-phosphate phosphatase wherein the plant promoter is RbcS, wherein the selectable marker is kanomycin resistance, wherein the transformed plant is more stress-tolerant, than an untransformed plant, wherein the monocotyledonous plant may be wheat or rice, and wherein the method of transformation may be particle bombardment mediated or *Agrobacterium* mediated, as well as the seeds, plant cells and regenerated plants therewith (see claims 1, 3-8, 10-12, and 14-18, see also Column 2 lines 38-67, column 3 lines 1-2, 20-36, Column 5 lines 39-41, Column 6 lines 49-54, Column 7 lines 3-8, 27-35, 45-60, Column 9 lines 44-55, Column 10 lines 18-27, column 11 lines 44-46, 56-67, Column 12 lines 1-19, Example 4, for example).

Claims 1-10, 14-26, 30-76 rejected under 35 U.S.C. 102(b) as being anticipated by Lebel et al (WO9946370).

The claims are drawn to a transgenic monocot plant or plant cell or protoplast transformed with a nucleic acid encoding an enzyme for trehalose biosynthesis, under control of an inducible promoter that confers low temperature stress, salt stress, or

Art Unit: 1638

water stress tolerance to the plant wherein the monocotyledonous plant is a rice or wheat plant, wherein the plant is additionally transformed with a second nucleic acid encoding an enzyme for trehalose biosynthesis, wherein the transgenic monocot plant includes a nucleic acid encoding a selectable marker, a seed produced by said transgenic plant, a transgenic plant regenerated from said seed, protoplast or plant cell, a method of conferring low-temperature stress, water stress, or salt stress tolerance to a monocot plant comprising transforming monocot plant cell or protoplast with a nucleic acid encoding an enzyme for trehalose biosynthesis, wherein the monocotyledonous plant is wheat or rice and wherein the plant cell or protoplast is transformed with a second nucleic acid encoding an enzyme for trehalose biosynthesis, and wherein the method of transformation is particle bombardment, or *Agrobacterium* mediated. The claims are further drawn to the methods and transformed plants and cells described above wherein the enzyme for trehalose biosynthesis is trehalose-6-phosphate synthase encoded by an *E. coli otsA* gene or trehalose-6-phosphate phosphatase encoded by an *E. coli otsB* gene, or a trehalose-6-phosphate synthase/trehalose-6-phosphate phosphatase fusion gene.

Lebel et al teach a monocotyledonous plant and plants cells transformed with both the *E. coli otsA* and *otsB* genes, as well as a construct containing an *E. coli otsA/otsB* fusion gene under control of an inducible promoter, wherein the selectable marker is a GUS reporter gene, wherein the transformed plant is more stress-tolerant, than an untransformed plant, wherein the monocotyledonous plant may be wheat or rice, and wherein the method of transformation may be particle bombardment mediated

or *Agrobacterium* mediated as well as the seeds and regenerated plants therewith (see page 2 third full paragraph, page 3 second and third paragraphs, page 4 first paragraph, page 13 paragraphs 2 and 3, Example 6, Example 9, Example 10 Examples 13-15, for example).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7, 9, 11-21, 23, 25, 27-42, 49-53, 55, 57, 59-69, 71, 73-74, 76-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Londesborough et al (US Patent 6130368) in view of Su et al (1998 Plant Physiology 117:913-922).

The claims are drawn to a transgenic monocot plant or plant cell or protoplast transformed with a nucleic acid encoding an enzyme for trehalose biosynthesis, under control of an inducible promoter that confers low temperature stress, salt stress, or water stress tolerance to the plant wherein the monocotyledonous plant is a rice or wheat plant, wherein the inducible promoter is a RbcS promoter or a stress and abscisic acid inducible promoter, wherein the plant is additionally transformed with a second nucleic acid encoding an enzyme for trehalose biosynthesis, wherein the transgenic monocot plant includes a nucleic acid encoding a selectable marker, a seed produced by said transgenic plant, a transgenic plant regenerated from said seed, protoplast or

Art Unit: 1638

plant cell, a method of conferring low-temperature stress, water stress, or salt stress tolerance to a monocot plant comprising transforming monocot plant cell or protoplast with a nucleic acid encoding an enzyme for trehalose biosynthesis, wherein the monocotyledonous plant is wheat or rice and wherein the plant cell or protoplast is transformed with a second nucleic acid encoding an enzyme for trehalose biosynthesis, and wherein the method of transformation is particle bombardment, or *Agrobacterium* mediated. The claims are further drawn to the methods and transformed plants and cells described above wherein the enzyme for trehalose biosynthesis is trehalose-6-phosphate synthase or trehalose-6-phosphate phosphatase.

Londesborough et al teach a monocotyledonous plant transformed with both the yeast trehalose-6-phosphate synthase and yeast trehalose-6-phosphate phosphatase wherein the plant promoter is RbcS, wherein the selectable marker is kanomycin resistance, wherein the transformed plant is more stress-tolerant, than an untransformed plant, wherein the monocotyledonous plant may be wheat or rice, and wherein the method of transformation may be particle bombardment mediated or *Agrobacterium* mediated, as well as the seeds, plant cells and regenerated plants therewith (see claims 1, 3-8, 10-12, and 14-18, see also Column 2 lines 38-67, column 3 lines 1-2, 20-36, Column 5 lines 39-41, Column 6 lines 49-54, Column 7 lines 3-8, 27-35, 45-60, Column 9 lines 44-55, Column 10 lines 18-27, column 11 lines 44-46, 56-67, Column 12 lines 1-19, Example 4, for example).

Londesborough et al do not teach a stress and abscisic acid-inducible promoter.

Su et al teach the Act1 promoter of rice which is a stress and abscisic acid-inducible promoter. Su et al also disclose why such promoters are used in transgenic plants modified for stress resistance by stating "However, under normal environmental conditions, overproduction of these compounds or proteins need extra energy and building blocks and may hamper normal growth of plants. Thus, it is desirable to generate transgenic plants that synthesize a high level of an osmoprotectant or a protein only under stress conditions" (see page 913 end of first paragraph).

Given the state of the art, the disclosures by Londesborough et al, and Su et al, and the predictability of success, it would have been obvious to one of ordinary skill in the art given the state of the art to modify the method disclosed by Londesborough et al by using the Act1 rice promoter disclosed by Su et al in the DNA construct so that the stress resistant genes would be transcribed only under stress conditions as suggested by Su et al.

Claims 80-83 are free of the prior art given the failure of the prior art to teach or reasonably suggest a transgenic monocot plant transformed with a plasmid wherein the plasmid is designated pSB109-TPSP.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brent Page whose telephone number is (514)-272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone

Art Unit: 1638

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

A handwritten signature in black ink, appearing to read 'David T. Fox', written in a cursive style.